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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

REBECCA MARTIN and MYRA HUGGINS, individually, and on behalf of all others similarly situated,

Plaintiffs,

v.

MDALGORITHMS, INC.; OBAGI COSMECEUTICALS LLC,

Defendants.

CASE NO.

CLASS ACTION COMPLAINT FOR:

1. **VIOLATION OF MISSOURI'S MERCHANDISING PRACTICES ACT;**
2. **VIOLATION OF FLORIDA'S DECEPTIVE TRADE PRACTICES ACT;**
3. **FRAUD/MISREPRESENTATION;**
4. **NEGLIGENT MISREPRESENTATION; AND**
5. **UNJUST ENRICHMENT**

DEMAND FOR JURY TRIAL

CLASS ACTION COMPLAINT

Rebecca Martin and Myra Huggins ("Plaintiffs"), individually, and on behalf of all others similarly situated, by and through their attorneys, bring this class action complaint against Defendants MDalgorithms, Inc. and Obagi Cosmeceuticals LLC (collectively "Defendants"). Plaintiffs allege the following based upon personal knowledge as well as investigation by counsel, and as to all other matters, upon information and belief. Plaintiffs further believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a class action lawsuit concerning Defendants' manufacturing, distribution, advertising, marketing, and sale of (1) MDalgorithms, Inc.'s MDacne Customized Treatment Cream (Benzoyl Peroxide 5%) and (2) Obagi Cosmeceuticals LLC's CLENZIderm M.D. Therapeutic Lotion Acne Treatment (Benzoyl Peroxide 5%) (collectively the "BPO Products"), which are alleged to contain benzene and/or degrade to form benzene—a carcinogen that has been linked to leukemia and other blood cancers.

2. Throughout this Complaint, references to federal law and Food and Drug Administration ("FDA") regulations are merely to provide context and are not intended to raise a federal question of law. All claims alleged herein arise out of violations of Missouri and Florida law, which in no way conflict, interfere with, or impose obligations that are materially different than those imposed by federal law.

3. Prior to placing the BPO Products into the stream of commerce and into the hands of consumers to use on their skin, Defendants knew or should have known that the BPO Products contained benzene, but misrepresented, omitted, and concealed this fact to consumers, including Plaintiffs and Class members, by not including benzene on the BPO Products' labels or otherwise warning consumers about its presence.

4. Plaintiffs and Class members reasonably relied on Defendants' representations that the BPO Products were safe, unadulterated, and free of any carcinogens that are not listed on the label.

5. Plaintiffs and Class members purchased BPO Products that contain benzene.

6. Because the BPO Products contain benzene, the Products are adulterated and misbranded under Missouri and Florida state law.

7. Defendants are therefore liable to Plaintiffs and Class members for misrepresenting and/or failing to disclose or warn that the BPO Products contain benzene and/or degrade to form benzene.

PARTIES

8. Plaintiff Rebecca Martin is a resident and citizen of Springfield, Missouri, located in Greene County. Within the applicable class period, including in 2023, Plaintiff purchased several of Defendant Obagi Cosmeceuticals LLC's CLINZIderm M.D. brand Therapeutic Lotion Acne Treatment (Benzoyl Peroxide 5%) products from a medical spa in Missouri and via online. When purchasing the BPO Products, Plaintiff reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer that the BPO Products were properly manufactured, free from defects, safe for their intended use, and not adulterated or misbranded. Plaintiff relied on these representations and warranties in deciding to purchase the BPO Products manufactured by Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff known that benzene was contained in the Products at the time of purchase and/or that the Products degraded to form benzene, Plaintiff would not have purchased and used the Products at all or would have paid significantly less for them. Plaintiff would have never paid a premium for BPO Products that contain the carcinogen benzene.

9. Plaintiff Myra Huggins is a resident and citizen of Pensacola, Florida, located in Escambia County. Within the applicable class period, including in 2023 and 2024, Plaintiff purchased MDacne Customized Treatment Cream (Benzoyl Peroxide 5%) and CLINZIderm M.D. Therapeutic Lotion Acne Treatment (Benzoyl Peroxide 5%). She purchased both products online. After purchasing the BPO Products, Plaintiff subjected both Products (i.e. MDacne Customized Treatment Cream and CLINZIderm M.D. Therapeutic Lotion Acne Treatment) to testing by an independent laboratory. Both BPO Products were found to contain excessive amounts of benzene—in amounts well above the maximum set by the FDA for drug products sold in the United States—thus rendering

the BPO Product dangerous to human health and illegal to sell. When purchasing the BPO Products, Plaintiff reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer that the BPO Products were properly manufactured, free from defects, safe for their intended use, and not adulterated or misbranded. Plaintiff relied on these representations and warranties in deciding to purchase the BPO Products manufactured by Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff known that benzene was contained in the Products at the time of purchase and/or that the Products degraded to form benzene, Plaintiff would not have purchased and used the Products at all or would have paid significantly less for them. Plaintiff would have never paid a premium for BPO Products that contain the carcinogen benzene.

10. Standing is satisfied by alleging economic injury. Here, Plaintiffs suffered economic injury when they spent money to purchase BPO Products they would not otherwise have purchased, or paid less for, absent Defendants' misconduct, as alleged herein. Members of the putative class have likewise suffered economic injuries in that they have spent money to purchase BPO Products they would not otherwise have purchased, or paid less for, absent Defendants' misconduct, as alleged herein.

11. Defendant MDalgorithms, Inc. is a Delaware corporation with headquarters at 22 Shlomzion Hamalka Street, Herzliya, Israel 4662 and a US-based principal place of business at 548 Market St., Suite 86774, San Francisco, California 94104. MDalgorithms, Inc manufactures MDacne Customized Treatment Cream (Benzoyl Peroxide 5%) in the United States and distributes this BPO Product from its San Francisco location.

12. Defendant Obagi Cosmeceuticals LLC is a Delaware limited liability company with its principal place of business at 3760 Kilroy Airport Way, Suite 500, Long Beach, California 90806.

13. Upon information and belief, Defendants engage in the manufacture, marketing, distribution and sale of over-the-counter drug products (including the BPO Products at issue) throughout the United States, including in Missouri and Florida. The BPO Products, including those purchased by Plaintiffs and Class members, are available for sale on Defendants' websites, www.mdacne.com and www.obagi.com, through third party websites like Amazon

(www.amazon.com), and are sold by various retailers both online and in their brick-and-mortar stores throughout the United States. Defendants authorized the false, misleading, and deceptive marketing, advertising, distribution, and sale of its BPO Products.

JURISDICTION AND VENUE

14. This Court has jurisdiction under the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2), because the matter in controversy exceeds the sum or value of $5,000,000 exclusive of interest and costs and is a class action in which there are more than 100 class members and many members of the class are citizens of a state different than Defendant.

15. Venue is proper in this Court pursuant to 28 U.S.C. § 1391, because Plaintiffs suffered injury as a result of Defendants' acts in this district, many of the acts and transactions giving rise to this action occurred in this district, Defendants conduct substantial business in this district, Defendants have intentionally availed themselves of the laws and markets of this district, and Defendants are subject to personal jurisdiction in this district.

FACTUAL ALLEGATIONS

I. Defendants' History in the Industry

16. Defendants manufacturer, market, distribute, and/or sell various skin care products, including the BPO Products.

17. Benzoyl peroxide is an active ingredient in all the BPO Products.

18. All of Defendant MDalgorithms, Inc.'s MDacne Customized Treatment Cream (Benzoyl Peroxide 5%) products are manufactured in the same manner.

19. All of Defendant Obagi Cosmeceuticals LLC's CLINZIderm M.D. brand Therapeutic Lotion Acne Treatment (Benzoyl Peroxide 5%) products are manufactured in the same manner.

20. Collectively, all lots of Defendants' BPO Products contain and/or or systematically degrade to form benzene. As noted below, this is supported by testing conducted by Valisure LLC ("Valisure") of 66 acne treatment products containing benzoyl peroxide (not including the BPO Products at issue), all of which tested positive for benzene at various levels ranging from 2,000 ppm

to 1.8 ppm. These results have been published in peer-reviewed literature.[1] Further, the specific BPO Products at issue—which were not subjected to testing by Valisure but were subjected to testing by Plaintiff Huggins—confirm that the BPO Products identified herein also contain and/or or systematically degrade to form benzene at excessive levels which render the Products dangerous to human health and illegal to sell in the United States.

21. The rates of degradation and benzene impurities in the BPO Products occur at a systematic rate.

II. Evidence of Benzene's Danger

22. Benzene is used primarily as a solvent in the chemical and pharmaceutical industries, as a starting material and intermediate in the synthesis of numerous chemicals, and in gasoline. The major United States source of benzene is petroleum. The health hazards of benzene have been recognized for over one hundred years.

23. "Human exposure to benzene has been associated with a range of acute and long-term adverse health effects and diseases, including cancer and haematological effects."[2]

24. A toxicity assessment by the Centers for Disease Control and Prevention has shown benzene can harm the central nervous system and may affect reproductive organs.[3]

25. According to the World Health Organization, "Benzene is a genotoxic carcinogen in humans and no safe level of exposure can be recommended."[4]

26. According to the National Cancer Institute, "[e]xposure to benzene increases the risk of developing leukemia and other blood disorders."[5]

27. According to the National Toxicology Program, benzene is "known to be a human carcinogen based on sufficient evidence of carcinogenicity from studies in humans."[6]

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[1] Kucera K, Zenzola N, Hudspeth A, Dubnicka M, Hinz W, Bunick CG, Dabestani A, Light DY. Benzoyl Peroxide Drug Products Form Benzene. Environ Health Perspect. 2024 Mar;132(3):37702. doi: 10.1289/EHP13984. Epub 2024 Mar 14. PMID: 38483533; PMCID: PMC10939128.
[2] https://www.who.int/publications/i/item/WHO-CED-PHE-EPE-19.4.2.
[3] https://www.atsdr.cdc.gov/toxprofiles/tp3.pdf.
[4] WHO Guidelines for Indoor Air Quality: Selected Pollutants (2010).
[5] https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/benzene.
[6] http://ntp.niehs.nih.gov/go/roc/content/profiles/benzene.pdf (emphasis in original).

28. Benzene has also been "found to be carcinogenic to humans" by the International Agency for Research on Cancer ("IARC"). Benzene was "[f]irst evaluated by IARC in 1974 . . . and was found to be carcinogenic to humans (Group 1), a finding that has stood since that time."[7] As noted by the IARC:

> In the current evaluation, the Working Group again confirmed the carcinogenicity of benzene based on *sufficient evidence* of carcinogenicity in humans, *sufficient evidence* of carcinogenicity in experimental animals, and *strong* mechanistic evidence. … The Working Group affirmed the strong evidence that benzene is genotoxic, and found that it also exhibits many other key characteristics of carcinogens, including in exposed humans. In particular, benzene is metabolically activated to electrophilic metabolites; induces oxidative stress and associated oxidative damage to DNA; is genotoxic; alters DNA repair or causes genomic instability; is immunosuppressive; alters cell proliferation, cell death, or nutrient supply; and modulates receptor-mediated effects.[8]

29. The FDA also recognizes that "[b]enzene is a carcinogen that can cause cancer in humans"[9] and classifies benzene as a "Class 1" solvent that should be "avoided" in drug manufacturing.[10] FDA guidance provides: "Solvents in Class 1 [e.g. benzene] should not be employed in the manufacture of drug substances, excipients, and drug products because of [its] unacceptable toxicity."[11]

30. In July 2021, the FDA conducted a "Health Hazard Evaluation" on "Multiple Aerosol Sunscreen Products" manufactured by Johnson & Johnson.[12] The evaluation was requested following testing which showed benzene levels ranging "from 11.2 to 23.6 ppm" in Johnson & Johnson's aerosol sunscreen products. Specifically, the agency requested "an evaluation of the likelihood and risks associated with using aerosol sunscreens that contain benzene 11.2 to 23.6 ppm," which "levels

[7] Benzene / IARC Working Group on the Evaluation of Carcinogenic Risks to Humans (2017: Lyon, France), at p. 33.
[8] *Id*. at 34.
[9] https://www.fda.gov/food/chemicals/questions-and-answers-occurrence-benzene-soft-drinks-and-other-beverages#q1.
[10] https://www.fda.gov/media/71737/download.
[11] *Id.*
[12] https://article.images.consumerreports.org/prod/content/dam/CRO-Images-2021/Health/12Dec/FDA_Benzene_in_Sunscreen_Assessment.

exceed the guideline value provided by ICH [Q3C][13] and USP[14]" limits, states the report. The evaluation concluded that serious adverse effects, including potential for "life-threatening" issues or "permanent impairment of a body function" were "likely to occur" at exposure levels within that range. In addition, the evaluation stated that "individuals with altered skin absorption (i.e., infants, elderly, broken skin) and individuals who are exposed to benzene from other sources . . . may be at greater risk."

31. On December 27, 2023, in response to reports of benzene contamination in various drug products, the FDA issued an "Alert," stating: "Drug manufacturers with a risk for benzene contamination should test their drugs accordingly and should not release any drug product batch that contains benzene above 2 ppm[.] … If any drug product batches with benzene above 2 ppm are already in distribution, the manufacturer should contact FDA to discuss the voluntary initiation of a recall[.]"[15]

32. "Even in trace amounts, benzene is known to pose a health risk from exposure routes that include inhalation, ingestion, dermal absorption, and skin or eye contact."[16]

33. As with other topically applied products, such as sunscreen, the application of BPO Products specifically increases the absorption rate of benzene through the skin, thereby increasing the risk of harm.[17] Indeed, "[d]irect exposure of the eyes, skin, or lungs to benzene can cause tissue injury and irritation."[18] Accordingly, The National Institute for Occupational Safety and Health ("NIOSH") recommends protective equipment be worn by workers exposed or expecting to be exposed to benzene at concentrations of 0.1 ppm and defines "inhalation, skin absorption, ingestion,

[13] The term "ICH" refers to The International Conference on Harmonization (ICH) Q3C Impurities: Residual Solvents guidance (December 1997), at https://www.fda.gov/media/71736/download?attachment.
[14] The term "USP" refers to United States Pharmacopeia (USP) Residual Solvents, at https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/generalChapter467Current.pdf.
[15] https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs.
[16] Hudspeth, A., et al., Independent Sun Care Product Screening for Benzene Contamination, Environmental Health Perspectives, 130:3, Online Publication 29 March 2022.
[17] *Valisure Detects Benzene in Sunscreen*, VALISURE BLOG (May 25, 2021), https://www.valisure.com/blog/valisure-news/valisure-detects-benzene-in-sunscreen/.
[18] *Facts About Benzene,* CENTERS FOR DISEASE CONTROL AND PREVENTION, https://emergency.cdc.gov/agent/benzene/basics/facts.asp.

skin and/or eye contact" as exposure routes or paths.[19]

34. The Environmental Protection Agency ("EPA") similarly recognizes the cancer risks of benzene, noting that "Benzene is classified as a 'known' human carcinogen (Category A) under the Risk Assessment Guidelines of 1986."[20] "[B]enzene is characterized as a known human carcinogen for all routes of exposure based on convincing human evidence as well as supporting evidence from animal studies."[21]

35. EPA has set 0.0005 ppm as the maximum permissible level of benzene in drinking water, with a stated goal of "zero."[22]

36. In its review of non-cancer adverse health effects of benzene, the EPA cited epidemiologic evidence that "support a threshold of benzene hematotoxicity[23] in humans in the 5-19 ppm range[.]"[24] As noted in the EPA's review, "[c]learly, if a significantly elevated risk of benzene poisoning is an indication of hematotoxicity, then certainly exposures to benzene at 5-19 ppm are hematotoxic."[25]

III. Discovery of Benzene in the BPO Products

37. On March 5, 2024, Valisure LLC ("Valisure") submitted a public citizens petition to the FDA requesting a recall and suspension of sales of benzoyl peroxide from the U.S. market. The petition was based on Valisure's findings that numerous BPO products contained elevated levels of benzene, a known human carcinogen.[26]

38. "Valisure operates an analytical laboratory that is accredited under International

[19] *NIOSH Pocket Guide to Chemical Hazards - Benzene*, THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH), https://www.cdc.gov/niosh/npg/npgd0049.html.
[20] https://cfpub.epa.gov/ncea/iris2/chemicallanding.cfm?substance_nmbr=276.
[21] *Id*.
[22] https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations.
[23] The term "hematotoxic" means "poisonous to the blood and to the organs and tissues involved in the production of blood, such as the bone marrow." https://clinicalinfo.hiv.gov/en/glossary/hematotoxic.
[24] EPA, Toxicological Review of Benzene (Noncancer Effects) (October 2002), at 38. https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0276tr.pdf.
[25] *Id*.
[26] https://assets-global.website-files.com/6215052733f8bb8fea016220/65e8560962ed23f744902a7b_Valisure%20Citizen%20Petition%20on%20Benzene%20in%20Benzoyl%20Peroxide%20Drug%20Products.pdf.

Organization for Standardization ('ISO/IEC') 17025:2017 standards for chemical testing (PJLA Accreditation Number 94238)," and it "is registered with the Drug Enforcement Administration (License # RV0484814)."[27] As an industry leader in independent chemical testing of medications, Valisure works with large private health care systems like Kaiser Permanente and governmental healthcare systems like the Military Health System through the U.S. Department of Defense.[28]

39. In its citizens petition, Valisure reported its testing results for benzene in various types of BPO drug products, mostly utilizing gas chromatography and detection by mass spectrometry ("GC-MS") instrumentation that allows mass spectral separation and utilizing selected ion chromatograms, along with Selected Ion Flow Tube-Mass Spectrometry ("SIFT-MS") for detection of benzene released into the air around certain BPO products. Valisure also used other orthogonal approaches for confirmation of a few select products.[29]

40. GC-MS "is generally considered one of the most accurate analyses available."[30] Indeed, the FDA used the same method to test for impurities like benzene in hand sanitizers.[31]

41. "The GC-MS method described in [Valisure's] petition utilized body temperature (37°C) for oven incubation. 40°C has been previously used for benzene analysis from liquid pharmaceuticals and beverages, and reduced false positive results compared with higher-temperature incubation."[32]

42. As reported, Valisure analyzed 66 different BPO containing drug products, both prescription and over-the-counter ("OTC") for the presence of benzene. Valisure acquired the products and incubated the products at 50°C[33] for 18 days, with samples measured at day 0, 4, 10, 14,

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[27] *Id.*

[28] Valisure Signs Agreement with Department of Defense to Independently Test & Quality Score Drugs. (August 8, 2023). PR Newswire. (https://www.prnewswire.com/newsreleases/valisure-signs-agreement-with-department-of-defense-to-independently-test--quality-score-drugs301895301.html).

[29] *Id.* at 10.

[30] *GC/MS Analysis*, Element, https://www.element.com/materials-testing-services/chemical-analysis-labs/gcms-analysis-laboratories.

[31] *Direct Injection Gas Chromatography Mass Spectrometry (GC-MS) Method for the Detection of Listed Impurities in Hand Sanitizers*, FDA (Aug. 24, 2020), https://www.fda.gov/media/141501/download.

[32] *Valisure Citizen Petition* at 10-11 (citations omitted).

[33] "50°C (122°F) is not only a reasonable temperature that 'the product may be exposed to during distribution and handling by consumers' but is an accepted incubation temperature used by the

and 18. These BPO containing products represented creams, lotions, gels, washes, liquids, and bars. As demonstrated below, results from this 50°C stability showed that every one of the 66 products contained some level of benzene ranging from a maximum of 2,000 ppm to 1.8 ppm.[34]

43. Valisure's findings with respect to its benzene testing of the BPO Product has been published in peer-reviewed literature.[35]

44. As noted above, independent testing conducted on Plaintiff Huggins BPO Products in particular also revealed benzene levels far above of the maximum set by FDA guidelines, thus rendering the BPO products harmful to human health and illegal to sell.

45. The BPO Products are not designed to contain benzene, and no amount of benzene is acceptable in acne treatment products such as the BPO Products manufactured, distributed, and sold by Defendant. Further, although Defendants lists the ingredients on the BPO Products' labels, Defendants fail to disclose on the Products' labeling or anywhere in its marketing that the BPO Products contain benzene or that the Products can degrade to form benzene.

46. Despite its knowledge that the BPO Products contain benzene, Defendants have failed to issue a voluntary recall of the BPO Products.

IV. Benzene Contamination Renders the BPO Products Adulterated, Misbranded, and Illegal to Sell

47. The BPO Products are "drugs" used to treat acne (i.e., *acne vulgaris*), formulated with a chemical called benzoyl peroxide, along with other inactive ingredients, to make acne treatment creams, washes, scrubs, and bars. Before being sold to the public, the BPO Products must be made in conformity with current good manufacturing practices and must conform to quality, safety, and purity specifications. Under the FDCA, a drug is adulterated "if it is a drug and the methods used in,

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pharmaceutical industry for performing accelerated stability studies with a duration of at least 3 months." *Id.* at 18-19 (citations omitted).

[34] *Id*. at 16-18.

[35] Kucera K, Zenzola N, Hudspeth A, Dubnicka M, Hinz W, Bunick CG, Dabestani A, Light DY. Benzoyl Peroxide Drug Products Form Benzene. Environ Health Perspect. 2024 Mar;132(3):37702. doi: 10.1289/EHP13984. Epub 2024 Mar 14. PMID: 38483533; PMCID: PMC10939128.

or the facilities or controls used for, its manufacture, processing, packaging, or holding do not confirm to or are not operated or administered in conformity with current good manufacturing practice…."[36]

48. Benzene is restricted by the FDA to 2 ppm where its use in manufacturing "is unavoidable in order to produce a drug product with a significant therapeutic advance."[37] Except in such "limited cases," Class 1 solvents such as benzene should not be employed in the manufacture of drug substances or drug products "because of their unacceptable toxicity."[38] Defendants' BPO Products do not meet this safe harbor exception. This is because the use of benzene in the manufacture of the BPO Products is not "unavoidable," nor does the use of benzene in BPO Products provide a "significant therapeutic advance." That is why, in December 2022, the FDA issued a statement alerting manufacturers to the risk of benzene contamination and warned that any drug product containing more than 2 ppm benzene was adulterated and should be recalled. This statement was updated on December 27, 2023, and still provides that drug manufacturers "should not release any drug product batch that contains benzene above 2 ppm," and further provides, "[i]f any drug product batches with benzene above 2 ppm are already in distribution, the manufacturer should contact FDA to discuss the voluntary initiation of a recall[.]"[39]

49. It is therefore illegal under federal law to manufacture and distribute drug products in the United States that contain benzene above 2 ppm.[40] Hence, within the past three years alone, the FDA has announced over a dozen recalls of various drug and cosmetic products identified as containing "low levels" or even "trace levels" of benzene, including certain hand sanitizers and

[36] 21 U.S.C. § 351(a)(2)(B).
[37] 2018 ICH Q3C guidance, at p. 5. US FDA, June 2017 (available at https://www.fda.gov/media/71737/download).
[38] *Reformulating Drug Products That Contain Carbomers Manufactured With Benzene*; Guidance for Industry – Final Guidance. US FDA, December 27, 2023 (citing 2018 ICH Q3C guidance at p. 5) (available at https://www.regulations.gov/document/FDA-2023-D-5408-0002).
[39] https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs. The FDA cannot force a drug manufacturer to recall a contaminated or adulterated drug. https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practice-cgmp ("While FDA cannot force a company to recall a drug, companies usually will recall voluntarily or at FDA's request").
[40] 21 U.S.C. § 351(a)(2)(B).

aerosol drug products like sunscreens and antiperspirants.[41]

50. It is also illegal to distribute benzene contaminated drug products under Missouri and Florida. For example, in Missouri, "[a] drug … shall be deemed to be adulterated: (1) If it consists in whole or part of any filthy, putrid, or decomposed substance; or (2) It has been produced, prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or … (6) If [its] purity or quality falls below [] that which it purports or is represented to possess."[42]

51. Because all of Defendants' BPO Products contain benzene above 2 ppm, the BPO Products (1) consist of a filthy, putrid, and/or decomposed substance (i.e. benzene), (2) have been produced under conditions whereby it is injurious to health (i.e. benzene exposure), (3) have a purity or quality that falls below that which it purports or is represented to possess. As a result, it is illegal under Missouri law for Defendants to distribute any of its BPO Products in the State of Missouri.

52. As alleged herein, Defendants' BPO Products contain more than 2 ppm benzene and have been distributed to residents of the states of Missouri and Florida, including Plaintiffs.

53. The manufacture of any misbranded or adulterated drug is prohibited under federal law,[43] and Missouri[44] and Florida[45] state law.

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[41] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/johnson-johnson-consumer-inc-issues-voluntary-recall-specific-neutrogenar-and-aveenor-aerosol; https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/edgewell-personal-care-issues-voluntary-nationwide-recall-banana-boat-hair-scalp-sunscreen-due-0; https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pg-issues-voluntary-recall-specific-old-spice-and-secret-aerosol-spray-antiperspirants-and-old-spice#:~:text=The%20Procter%20%26%20Gamble%20Company%20(NYSE,level%20due%20to%20the%20presence.

[42] Mo. Rev. Stat. § 196.095 (1), (2), (6).

[43] 21 U.S.C. §331(g).

[44] Mo. Rev. Stat. § 196.015(1) ("The following acts and the causing thereof within the state of Missouri are hereby prohibited: (1) The manufacture, sale, or delivery, holding or offering for sale any … drug … that is adulterated or misbranded").

[45] *See* Fla. Stat. § 499.005(1) ("It is unlawful for a person to perform or cause the performance of any of the following acts in this state: (1) The manufacture, repackaging, sale, delivery, or holding or offering for sale of any drug, device, or cosmetic that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use.").

54. The introduction into commerce of any misbranded or adulterated drug is similarly prohibited.[46]

55. The receipt in interstate commerce of any adulterated or misbranded drug is also unlawful.[47]

56. Among the ways a drug may be adulterated are:

> If it consists in whole or in part of any filthy, putrid, or decomposed substance; or . . . whereby it may have been rendered injurious to health; . . . .[48]

57. Among the ways a drug may be misbranded include:

> (1) The dissemination of any false advertisement; [49]
> (2) The using, on the labeling of any drug or in any advertising related to such drug, of any representation or suggestion that … such drug complies with the provisions of such section;[50] or
> (3) If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.[51]

58. Defendants could have avoided any potential for benzene contamination in the BPO Products by changing the manufacturing process or raw ingredients, and the BPO Products could have been sold with absolutely no benzene in them. Specifically, BPO as a raw material is known to

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[46] Mo. Rev. Stat. § 196.015(1); Cal. Health & Safety Code § 111305 ("It is unlawful for any person to receive in commerce any drug or device that is adulterated or to deliver or proffer for delivery any drug or device."); Fla. Stat. § 499.005(1).

[47] Mo. Rev. Stat. § 196.015(3); Cal. Health & Safety Code § 111305 ("It is unlawful for any person to receive in commerce any drug or device that is adulterated or to deliver or proffer for delivery any drug or device.").

[48] 21 U.S.C. §351(a)(2)(B). *See also* Mo. Rev. Stat. § 196.095(1) ("A drug or device shall be deemed to be adulterated: (1) If it consists in whole or part of any filthy, putrid, or decomposed substance"); Fla. Stat. § 499.006(1) & (2) ("A drug or device is adulterated, if any of the following apply: (1) It consists in whole or in part of any filthy, putrid, or decomposed substance[;] (2) It has been produced, prepared, packed, or held under conditions whereby it could have been contaminated with filth or rendered injurious to health.").

[49] Mo. Rev. Stat. § 196.015(5); Fla. Stat. § 499.007(1) (A drug is misbranded "[i]f its labeling is in any way false or misleading.").

[50] Mo. Rev. Stat. § 196.015(11).

[51] Fla. Stat. § 499.007(10) (A drug is misbranded "[i]f it is dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling of the drug.").

be thermally stable at purities as high as 75% up to temperatures of 98°C.[52] Valisure also evaluated pure BPO reference powder in its GC-MS analytical system and found no evidence of the instability and formation of benzene seen in formulated final products of BPO containing acne treatments.[53] Thus, if BPO is inherently stable as a pure, crystalline powder, a reformulated product that focuses on substantially reducing or entirely preventing the degradation of BPO into benzene could potentially be developed.[54]

59. The mere presence of benzene in the BPO Products renders the Products adulterated, misbranded, and illegal to sell. As such, the BPO Products have no economic value and are worthless. Worse, as manufactured, the levels of benzene contained in the BPO Products render them "dangerous to health" under the conditions of use prescribed in the labeling and advertising.[55]

60. As the FDA's July 2021 Health Hazard Evaluation concluded, serious adverse effects, including potential for "life-threatening" issues or "permanent impairment of a body function" were "likely to occur" at benzene exposure levels between 11.2 to 23.6 ppm.[56]

61. Similarly, in its review of the non-cancer effects of benzene, the EPA cites to studies in the medical literature which "support a threshold of benzene hematotoxicity in humans in the 5-19 ppm range, in broad agreement with the emerging exposure-response range that is apparent from the epidemiologic studies[.]"[57]

62. Defendants engaged in fraudulent, unfair, deceptive, misleading, and/or unlawful conduct stemming from its misrepresentations and omissions regarding benzene in its BPO Products.

63. If Defendants had disclosed to Plaintiffs and putative Class members that the BPO Products contain benzene and/or would degrade to form benzene, Plaintiffs and putative Class

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[52] *Valisure Citizens Petition* at 25 (citation omitted).
[53] *Id.*
[54] *See id.* at 25-26.
[55] Fla. Stat. § 499.007(10) (A drug is misbranded "[i]f it is dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling of the drug.").
[56] https://article.images.consumerreports.org/prod/content/dam/CRO-Images-2021/Health/12Dec/FDA_Benzene_in_Sunscreen_Assessment.
[57] EPA, Toxicological Review of Benzene (Noncancer Effects) (October 2002), at 38. https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0276tr.pdf.

members would not have purchased the BPO Products.

64. As manufacturers, distributors, and sellers of acne treatment products, Defendants had and have a duty to ensure that their BPO Products did not and do not contain excessive (or any) level of benzene, including through regular testing, especially before injecting the BPO Products into the stream of commerce for consumers to use on their skin.[58] This includes testing of raw materials and finished product batches prior to release to ensure they meet appropriate specifications for identity, strength, quality, and purity.[59] But Defendants made no reasonable effort to test their BPO Products for the presence of benzene or test whether the Products could degrade to form benzene over the course of the shelf-life of the Products. Nor did Defendants disclose to Plaintiffs in any advertising or marketing that their BPO Products contained benzene and/or could degrade to form benzene. To the contrary, Defendants represented the BPO Products were of merchantable quality, safe to use as prescribed, complied with federal and state law, and did not contain carcinogens or other impurities such as benzene.

V. Defendants' Knowledge, Misrepresentations, Omissions, and Concealment of Material Deceived Plaintiffs and Reasonable Consumers

65. It is well known that BPO degrades to form benzene when exposed to heat over time. This process was first reported in scientific literature as early as 1936.[60]

66. The issue of BPO decomposition into benzene has been previously identified and acted upon in industries other than in the acne treatment product industry.

67. For example, at least one patent application was filed by the chemical company Akzo Nobel N.V. in 1997 which "relates to a method for reducing the rate of free benzene and/or benzene derivative formation in BPO formulations based on organic plasticizers, such as pastes, emulsions,

[58] 21 CFR 211.84; 21 CFR 211.160.
[59] 21 CFR 211.165.
[60] H. Erlenmeyer and W. Schoenauer, *Über die thermische Zersetzung von Di-acyl-peroxyden,* HELU. CHIM. ACTA, 19, 338 (1936), https://onlinelibrary.wiley.com/doi/10.1002/hlca.19360190153.

suspensions, dispersions and the like."[61]

68. In the polymer manufacturing industry, BPO's decomposition into benzene has been studied and concern was raised specifically regarding the carcinogenic implications of the presence of benzene. In 1994, a paper was published[62] by researchers at Denmark's Department of Environmental Chemistry titled "Formation of benzene by hardeners containing benzoyl peroxide and phthalates" and stated:

> Recently, during the investigation of benzene residues in chemical products (Rastogi 1993a),[63] it was observed that the benzene content in benzoyl peroxide containing hardeners of two component repair-sets (fillers, elastomers) were >2 % (w/w) [20,000 ppm]. Benzene is carcinogenic (IARC 1982), and its use in consumer and industrial products is generally avoided.

69. The study continues with heating of various BPO-containing products at 34°C, 50°C and 80°C, finding substantial benzene formation at elevated temperatures, even exceeding levels found in Valisure's March 2024 public citizens petition. Furthermore, similar to Valisure's results, Rastogi finds that only formulations of BPO are unstable, while BPO alone is relatively stable:

> Even heating of BPO-phthalate mixtures at 50°C produced significant amounts of benzene (approximately 0.3% [3,000 ppm]), while no benzene production was detected when benzoyl peroxide was heated alone at this temperature (Table 2).[64]

70. The referenced 1993 Rastogi article above, titled "Residues of Benzene in Chemical Products," has also been flagged by the EPA as part of its Health & Environmental Research Online ("HERO") system.[65]

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[61] Borys F. SchafranBryce Milleville (1997). "Reduction of benzene formation in dibenzoyl peroxide formulations." Akzo Nobel N.V. Worldwide application, WO1997032845A1. (https://patents.google.com/patent/WO1997032845A1/en)

[62] Rastogi SC. Formation of benzene by hardeners containing benzoyl peroxide and phthalates. *Bull Environ Contam Toxicol*. 1994 Nov;53(5):747-52. doi: 10.1007/BF00196949. PMID: 7833612.

[63] Rastogi, S.C. Residues of benzene in chemical products. Bull. Environ. Contam. Toxicol. 50, 794-797 (1993). https://doi.org/10.1007/BF00209940.

[64] *Id.*

[65] US Environmental Protection Agency. Health & Environmental Research Online (HERO). "Residues of Benzene in Chemical Products." HERO ID 2894703 (http://hero.epa.gov/hero/index.cfm/reference/details/reference__id/2894703).

71. Chemical evidence of carcinogenicity has been reported since at least 1981.[66] Multiple studies in the 1980s were conducted using animal models that suggested carcinogenic potential of benzoyl peroxide, including the use of commercial drug formulations of BPO like that of the BPO Products at issue.[67]

72. In 1991, FDA posted an amendment to the monograph for OTC topical acne drug products because, "the agency became aware of a 1981 study by Slage, et al. ([FDA] Ref. 1) that raised a safety concern regarding benzoyl peroxide as a tumor promoter in mice and a 1984 study by Kurokawa, et al. ([FDA] Ref. 2) that reported benzoyl peroxide to have tumor initiation potential," leading FDA to determine that "further study is necessary to adequately assess the tumorigenic potential of benzoyl peroxide."[68]

73. By 2010, FDA published a final monograph on benzoyl peroxide along with summarizing results from further studies on the potential carcinogenicity of benzoyl peroxide and actions of the FDA Advisory Committee. This final monograph stated: "The Committee recommended, by a four-to-three vote (with one abstention), that the known safety data regarding the tumor promoting potential of benzoyl peroxide should be communicated to consumers. Because this data was inconclusive, the Committee unanimously agreed that the word, "cancer" should not be included in the labeling of acne drug products containing benzoyl peroxide. The Committee was concerned that the word "cancer" would cause consumers to avoid using these products (even though

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[66] Slaga TJ, Klein-Szanto AJ, Triplett LL, Yotti LP, Trosko KE. Skin tumor-promoting activity of benzoyl peroxide, a widely used free radical-generating compound. Science. 1981 Aug 28;213(4511):1023-5. doi: 10.1126/science.6791284. PMID: 6791284.

[67] Kurokawa Y, Takamura N, Matsushima Y, Imazawa T, Hayashi Y. *Studies on the promoting and complete carcinogenic activities of some oxidizing chemicals in skin carcinogenesis.* Cancer Lett. 1984 Oct;24(3):299-304. doi: 10.1016/0304-3835(84)90026-0. PMID: 6437666; Pelling JC, Fischer SM, Neades R, Strawhecker J, Schweickert L. *Elevated expression and point mutation of the Ha-ras proto-oncogene in mouse skin tumors promoted by benzoyl peroxide and other promoting agents*. Carcinogenesis. 1987 Oct;8(10):1481-4. doi: 10.1093/carcin/8.10.1481. PMID: 3115617; 81 O'Connell JF, Klein-Szanto AJ, DiGiovanni DM, Fries JW, Slaga TJ. *Enhanced malignant progression of mouse skin tumors by the free-radical generator benzoyl peroxide.* Cancer Res. 1986 Jun;46(6):2863-5. PMID: 3084079; 82 Iversen OH. *Carcinogenesis studies with benzoyl peroxide (Panoxyl gel 5%)*. J Invest Dermatol. 1986 Apr;86(4):442-8. doi: 10.1111/1523-1747.ep12285787. PMID: 3091706.

[68] Food and Drug Administration. *Proposed Rule: Reclassifies benzoyl peroxide from GRASE to Category III.* (August 7, 1991) Federal Register, 56FR37622. pp 37622 - 37635 (https://cdn.loc.gov/service/ll/fedreg/fr056/fr056152/fr056152.pdf#page=178).

the data were inconclusive).[69]

74. In 2020, the FDA started working with companies to identify benzene in products, which resulted in product recalls of hand sanitizers, sunscreens, and deodorants. In 2021, an independent chemical analysis by Valisure of hundreds of sunscreens and after-sun care products from 69 brands found 27% of the batches had significant levels of benzene above 2 ppm.[70]

75. Thus, by 2021, Defendants were well-aware of benzene contamination issues in their BPO Products and in products of their competitors.

76. Further, Defendants, which markets themselves as merchandisers of quality acne treatment products that and employs high-level scientists, chemists, and researchers to formulate and/or decide which drug products to label and sell for public use, were aware of the well-known chemical processes that degrade their BPO Products into benzene when exposed to commonly used temperatures and conditions.

77. Defendants, as large, sophisticated corporations in the business of manufacturing, distributing, and selling products containing BPO, knew or should have known the BPO Products were contaminated with excess levels of benzene and that testing the BPO Products for benzene was necessary to protect Plaintiffs and Class members from harmful levels of benzene exposure.

78. Defendants' use of BPO put it on notice of the excessive levels of benzene in the BPO Products.

79. Notwithstanding this knowledge, Defendants failed to appropriately and adequately test their BPO Products for the presence of benzene to protect Plaintiffs and Class members from dangerous levels of benzene exposure.

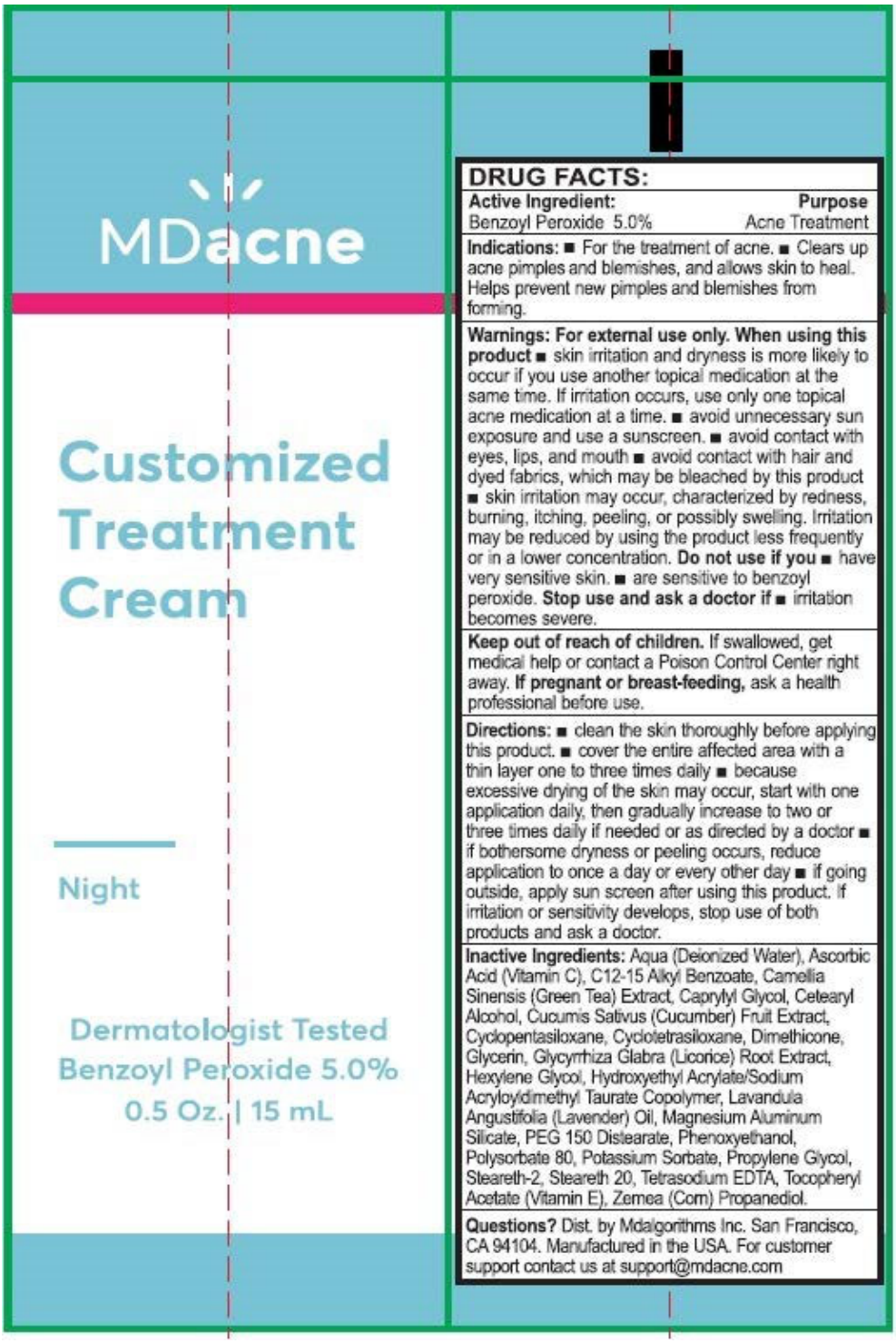
80. Defendants sold, and continue to sell, BPO Products during the class period despite their knowledge of the risk of benzene contamination.

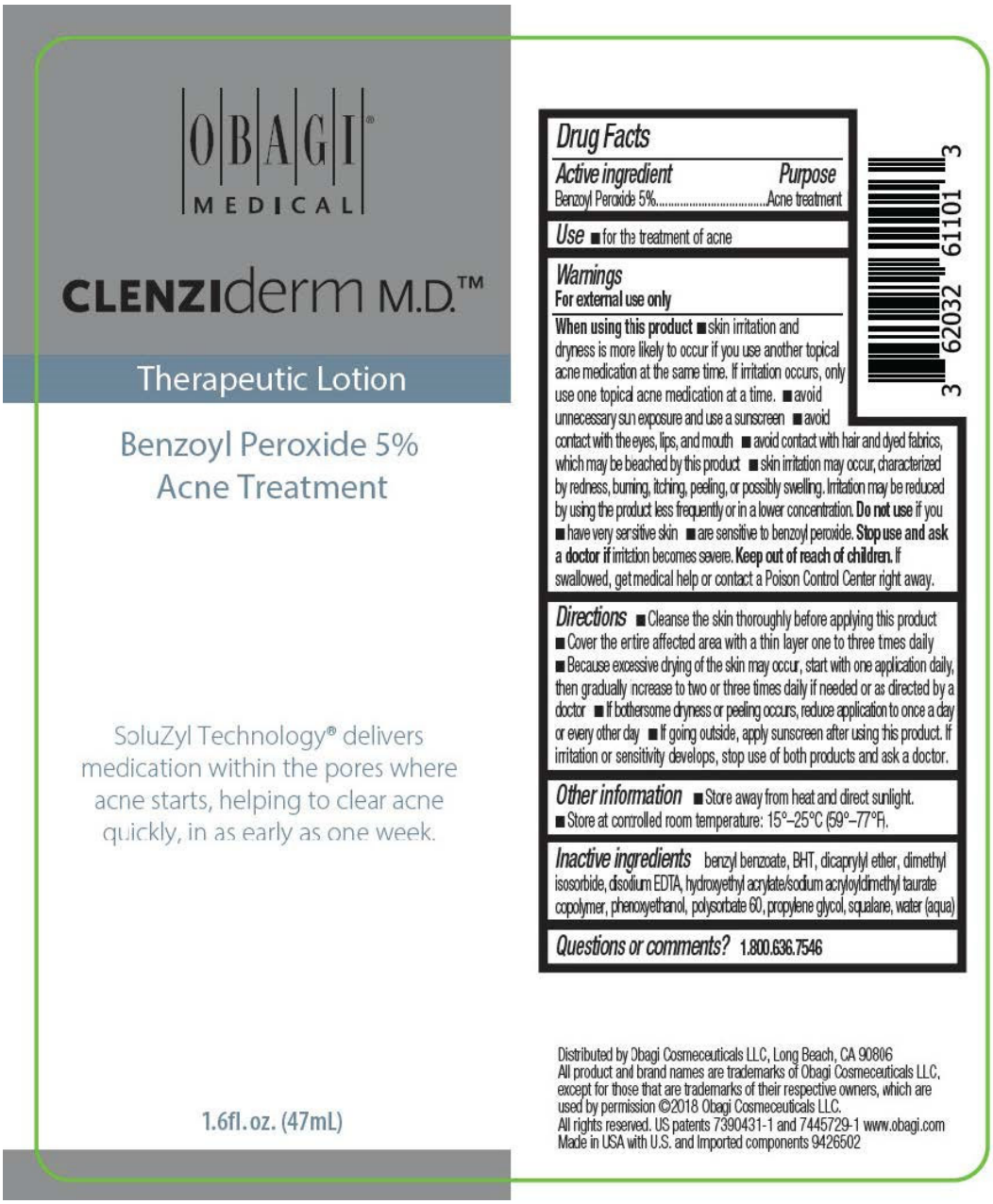
81. Benzene is not listed on the BPO Products' labels as an ingredient, nor is there any warning about the inclusion (or even potential inclusion) of benzene in the BPO Products. The

[69] Food and Drug Administration. Final Monograph. (March 4, 2010) Federal Register, 75FR9767. (https://www.gpo.gov/fdsys/pkg/FR-2010-03-04/pdf/2010-4424.pdf).

[70] Valisure Citizen Petition on Benzene in Sunscreen and After-sun Care Products, May 24, 2021.

following images shows an example:





82. Plaintiffs have standing to represent members of the putative Class because there is sufficient similarity between the specific BPO Product purchased by Plaintiffs and the other BPO Products not purchased by Plaintiffs. Specifically, each and every one of the BPO Products (i) are marketed in substantially the same way – as an acne treatment— and (ii) fail to include labeling indicating to consumers that the BPO Products contain benzene and/or degrade into benzene. Accordingly, the misleading effect of all the BPO Products' labels are substantially the same.

83. Defendants have engaged in deceptive, untrue, and misleading advertising by making

representations by failing to warn about the presence of benzene in the BPO Products.

84. As alleged, the presence of benzene in the BPO Products renders the BPO Products misbranded and adulterated and therefore illegal and unfit for sale in trade or commerce. Plaintiffs would not have purchased the BPO Products had they been truthfully and accurately labeled.

85. Had Defendants adequately tested its BPO Products for benzene and other carcinogens and impurities, it would have discovered its BPO Products contain benzene and/or degrade to form benzene —at levels above 2 ppm—making the BPO Products illegal to market, distribute, or sell as drugs in the United States.

86. Accordingly, Defendants knowingly, recklessly, or at least negligently, introduced the contaminated, adulterated, and misbranded BPO Products into the U.S. market.

87. Defendants' concealment was material and intentional because people are concerned with what is contained in the products they are putting onto and into their bodies. Consumers such as Plaintiffs and Class members make purchasing decisions based on the representations made on the BPO Products' labeling, including the ingredients listed.

VI. Injuries to Plaintiffs and Class Members

88. When Plaintiffs purchased Defendants' BPO Products, Plaintiffs did not know, and had no reason to know, that Defendants' BPO Products contained and/or would degrade into the harmful carcinogen benzene. Not only would Plaintiffs not have purchased Defendants' BPO Products had they known the Products contained and/or would degrade into benzene, but they would also not have been capable of purchasing them if Defendants had done as the law required and tested the BPO Products for benzene and other carcinogens and impurities.

89. Consumers lack the ability to test or independently ascertain or verify whether a product contains unsafe substances, such as benzene, especially at the point of sale, and therefore must rely on Defendants to truthfully and honestly report on the BPO Products' packaging and labeling what the Products contain.

90. Further, given Defendants' position as a leader in the acne treatment market, Plaintiffs and reasonable consumers trusted and relied on Defendants' representations and omissions regarding the presence of benzene in the BPO Products.

91. Defendants' false and misleading omissions and deceptive misrepresentations regarding the presence of benzene in the BPO Products are likely to continue to deceive and mislead reasonable consumers and the public, as it has already deceived and misled Plaintiffs and the Class members.

92. Plaintiffs and Class members bargained for products free of contaminants and dangerous substances. Plaintiffs and Class members were injured by the full purchase price of the BPO Products because the Products are worthless, as they are adulterated and contain harmful levels of benzene, and Defendants failed to warn consumers of this fact. Such illegally sold products are worthless and have no value.

93. As a proximate result thereof, Plaintiffs and Class members are entitled to statutory and punitive damages, attorneys' fees and costs, and any further relief this Court deems just and proper.

94. All conditions precedent to the prosecution of this action have occurred, and/or have been performed, excused, or otherwise waived.

CLASS ALLEGATIONS

95. Plaintiffs, individually and on behalf of all others similarly situated, bring this class action pursuant to Fed. R. Civ. P. 23.

96. Plaintiffs seek to represent classes defined as:

Missouri Class

All persons who purchased the BPO Products in the State of Missouri for personal or household use within the applicable limitations period.

Florida Class

All persons who purchased the BPO Products in the State of Florida for personal or household use within the applicable limitations period.

97. Excluded from the Class are: (1) any Judge or Magistrate presiding over this action and any members of their families; (2) Defendants, Defendants' subsidiaries, parents, successors, predecessors, and any entities in which Defendants or their parents and any entities in which

Defendants have a controlling interest and their current or former employees, officers, and directors; and (3) individuals who allege personal bodily injury resulting from the use of the BPO Products.

98. Plaintiffs reserve the right to modify, change, or expand the definitions of the Class based upon discovery and further investigation.

99. *Numerosity*: The Class is so numerous that joinder of all members is impracticable. The Class likely contains hundreds of thousands of members based on publicly available data. The Class is ascertainable by records in Defendants' possession.

100. *Commonality*: Questions of law or fact common to the Class include:

a. Whether the BPO Products contain benzene;

b. Whether a reasonable consumer would consider the presence of benzene in the BPO Products to be material;

c. Whether Defendants knew or should have known that the BPO Products contains benzene;

d. Whether Defendants misrepresented that the BPO Products contain and/or degrade into benzene;

e. Whether Defendants failed to disclose that the BPO Products contain and/or degrade into benzene;

f. Whether Defendants concealed that the BPO Products contain and/or degrade into benzene;

g. Whether Defendants engaged in unfair or deceptive trade practices;

h. Whether Defendants violated the state consumer protection statutes alleged herein;

i. Whether Defendants were unjustly enriched; and

j. Whether Plaintiffs and Class members are entitled to damages.

101. *Typicality*: Plaintiffs' claims are typical of the claims of Class members. Plaintiffs and Class members were injured and suffered damages in substantially the same manner, have the same claims against Defendants relating to the same course of conduct, and are entitled to relief under the same legal theories.

102. *Adequacy*: Plaintiffs will fairly and adequately protect the interests of the Class and

has no interests antagonistic to those of the Class. Plaintiffs have retained counsel experienced in the prosecution of complex class actions, including actions with issues, claims, and defenses similar to the present case. Counsel intends to vigorously prosecute this action.

103. *Predominance and superiority*: Questions of law or fact common to Class members predominate over any questions affecting individual members. A class action is superior to other available methods for the fair and efficient adjudication of this case because individual joinder of all Class members is impracticable and the amount at issue for each Class member would not justify the cost of litigating individual claims. Should individual Class members be required to bring separate actions, this Court would be confronted with a multiplicity of lawsuits burdening the court system while also creating the risk of inconsistent rulings and contradictory judgments. In contrast to proceeding on a case-by-case basis, in which inconsistent results will magnify the delay and expense to all parties and the court system, this class action presents far fewer management difficulties while providing unitary adjudication, economies of scale and comprehensive supervision by a single court. Plaintiffs are unaware of any difficulties that are likely to be encountered in the management of this action that would preclude its maintenance as a class action.

104. Accordingly, this class action may be maintained pursuant to Fed. R. Civ. P. 23(b)(3).

COUNT I

Violation of the Missouri Merchandising Practices Act, Mo. Rev. Stat. § 407.010, *et seq.* (On Behalf of Plaintiff Martin and the Missouri Class)

105. Plaintiff Martin incorporates by reference and re-allege each and every allegation contained above, as though fully set forth herein.

106. Plaintiff Martin brings this Count I individually and on behalf of the Missouri Class against Defendant Obagi Cosmeceuticals LLC.

107. The acts and practices engaged in by Defendant, and described herein, constitute unlawful, unfair and/or fraudulent business practices in violation of the Missouri Merchandising Practices Act, Mo. Rev. Stat. § 407.010, *et seq.*

108. Defendant engaged in unlawful practices including deception, false promises, misrepresentation, and/or the concealment, suppression, or omission of material facts in connection with the sale, distribution or advertisement of the BPO Products, in violation of Mo. Rev. Stat. § 407.020.

109. Plaintiff and the Class members purchased the BPO Products, Products that were falsely represented, as stated above, in violation of the Missouri Merchandising Practices Act, and as a result, Plaintiff and the Class members suffered economic damages in that the BPO Products were worth less than the product they thought they had purchased had Defendants' representations been true.

COUNT II

Violation of the Florida's Deceptive and Unfair Trade Practices Act, Fla. Stat. §§ 501.201-213 (On Behalf of Plaintiff Huggins and the Florida Class)

110. Plaintiff Huggins incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

111. Plaintiff Huggins brings this Count II individually and on behalf of the Florida Class against Defendants.

112. The Florida Deceptive and Unfair Trade Practices Act ("FDUTPA") renders unlawful unfair methods of competition, unconscionable acts or practice, and unfair or deceptive acts or practices in the conduct of any trade or commerce. § 501.204, Fla. Stat.

113. Among other purposes, FDUTPA is intended "[t]o protect the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce." § 501.202, Fla. Stat.

114. As alleged herein, Plaintiff has suffered injury in fact and lost money as a result of Defendants' conduct because she purchased the BPO Products from Defendants in reliance on Defendants' representation that the BPO Products were safe and effective and were not adulterated with dangerous levels of benzene, a known human carcinogen.

115. As alleged herein, Defendants' actions are deceptive and in clear violation of FDUTPA, entitling Plaintiff and the Class to damages and relief under Fla. Stat. §§ 501.201-213.

116. Defendants have engaged, and continue to engage, in conduct that is likely to deceive members of the public. This conduct includes representing in their labels that their BPO Products are safe, which is untrue, and failing to make any mention that the Products are adulterated with dangerous levels of benzene.

117. By committing the acts alleged above, Defendants have engaged in unconscionable, deceptive, or unfair acts or practices, which constitute unfair competition within the meaning of FDUTPA.[71]

118. Consumers, such as Plaintiff, reasonably rely on Defendants' representations of the BPO Products' safety, and the injuries claimed herein resulted from ordinary use of the Products. Consumers, such as Plaintiff, could not have reasonably avoided such injury.

119. Florida Statutes, Section 501.204, makes unfair and/or deceptive trade practices in the conduct of any trade or commerce illegal.

120. Florida Statutes, Section 501.211, creates a private right of action for individuals who are aggrieved by an unfair and/or deceptive trade practice by another person.

121. Florida Statutes, Section 501.2105, provides that the prevailing party in litigation arising from a cause of action pursuant to Chapter 501 shall be entitled to recover attorney's fees within the limitations set forth therein form the non-prevailing party.

122. Florida Statutes, Section 501.213, provides that any remedies available under Chapter 501 are in addition to any other remedies otherwise available for the same conduct under state or local law.

123. Florida Statutes, Section 501.203 (3)(c), states that a person has violated the FDUTPA if he violates "any law, statute, rule, regulation, or ordinance which proscribes unfair, deceptive, or unconscionable acts or practices."

[71] Defendants' conduct violates Section 5 of the Federal Trade Commission "("FTC") Act, 15 U.S.C. § 45, which prohibits unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.

124. Defendants are engaged in the practice of manufacturing, marketing, distributing, selling and otherwise placing into the stream of commerce BPO Products. Such activity constitutes trade and commerce as defined by Sections 501.203(8) Fla. Stat., and is thus subject to FDUPTA.

125. As a result of Defendants' unfair and deceptive trade practices, Plaintiff and the putative Class s are entitled to an award of attorney's fees pursuant to FDUTPA, Florida Statutes, Section 501.2105, if they prevail.

126. Defendants' conduct with respect to the labeling, advertising, marketing, and sale of their BPO Products is unfair because Defendant's conduct was immoral, unethical, unscrupulous, or substantially injurious to consumers and the utility of its conduct, if any, does not outweigh the gravity of the harm to its victims.

127. On behalf of Plaintiff and the putative Class, Plaintiffs seek an order entitling them to recover all monies spent on the Defendants' BPO Products, which were acquired through acts of fraudulent, unfair, or unlawful competition.[72] In addition, the measure of restitution should be full refund of the purchase price insofar as the BPO Products are worthless and illegal to sell in the United States. But for Defendants' misrepresentations and omissions, Plaintiff would have paid nothing for BPO Products that contain benzene and/or degrade into benzene under ordinary conditions. Indeed, there is no discernible "market" for an over-the-counter acne product that is adulterated with dangerous levels of a known human carcinogen. As recognized by the WHO, "[b]enzene is carcinogenic to humans, and no safe level of benzene can be recommended."[73] As a result, the Defendants' BPO Products are rendered valueless.

128. Wherefore, Plaintiff and members of the Class are entitled to a full refund in the amount they spent on the Defendants' BPO Products.

COUNT III

Fraud/Misrepresentation
(On Behalf of all Plaintiffs against Defendants)

129. Plaintiffs incorporate by reference and re-allege each and every allegation contained

[72] Section 501.211(2) provides that "a person who has suffered a loss as a result of a [FDUTPA] violation ... may recover actual damages . . . ."
[73] https://www.who.int/ipcs/features/benzene.pdf.

above, as though fully set forth herein.

130. Plaintiffs bring this Count III on behalf of the Missouri and Florida Classes against Defendants.

131. Defendants intentionally and knowingly falsely concealed, suppressed and/or omitted material facts including as to the standard, quality or grade of the BPO Products.

132. Due to Defendants' fraudulent conduct, Plaintiffs and the other Class members have suffered actual damages.

133. Defendants knew or should have known that the BPO Products contain benzene and/or degrade into benzene when used as directed.

134. Defendants knew or should have known that their concealment and suppression of material facts was false and misleading and knew the effect of concealing those material facts.

135. Defendants acted with malice, oppression, and fraud.

136. Defendants knew or should have known of the dangers associated with benzene in its BPO Products based on regulatory studies and regulatory guidance.

137. Defendants were obligated to inform Plaintiffs and the other Class members of the dangers associated with benzene in the BPO Products due to their exclusive and superior knowledge of the Products.

138. Plaintiffs and other Class members also expressly reposed a trust and confidence in Defendants because of their dealings as a healthcare entity and with Plaintiffs and other Class members as their customers.

139. Plaintiffs and the other Class members would not have purchased the BPO Products but for Defendants' omissions and concealment of material facts regarding the nature and quality of the Products, or would have paid less for the Products.

140. Plaintiffs and Class members were justified in relying on Defendants' misrepresentations and/or omissions.

141. As alleged herein, Plaintiffs and the Class members have suffered injury in fact and lost money as a result of Defendants' conduct because they purchased BPO Products from Defendants in reliance on Defendants' misrepresentation and/or omissions that the BPO Products were safe to

use as directed.

142. Wherefore, as a direct and proximate result thereof, Plaintiffs and members of the Class are entitled to injunctive and equitable relief, and a full refund in the amount they spent on the BPO Products.

COUNT IV

Negligent Misrepresentation
(On Behalf of all Plaintiffs against Defendants)

143. Plaintiffs incorporate by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

144. Plaintiffs bring this Count IV on behalf of the Missouri and Florida Classes against Defendants.

145. Defendants owed a duty of reasonable care to Plaintiffs and the Class members in the labeling, manufacturing, sale, and distribution of its BPO Products.

146. Defendants also had a duty to exercise reasonable care in properly and accurately representing the safety of its BPO Products to consumers, including Plaintiffs and the Class members.

147. Defendants failed to exercise ordinary care when making the misrepresentations and/or omissions in their marketing and labeling, claiming that their BPO Products were safe.

148. Defendants negligently and falsely misrepresented facts regarding the safety of their BPO products to Plaintiffs and the Class members.

149. Defendants knew or should have known that the misrepresentations regarding the safety of their BPO Products was misleading. Defendants knew or should have known that these misrepresentations would induce Plaintiffs and the Class members to purchase the BPO Products in reliance of Defendants' claims.

150. As a direct and proximate cause of Defendants' negligent misrepresentations, Plaintiffs and the Class members have suffered harm.

151. Defendants' misrepresentations were material and substantial factors in Plaintiffs and

Class members purchasing and paying for the BPO Products.

152. Defendants intended, or had reckless disregard, to induce Plaintiffs and Class members to purchase its BPO Products based on its misrepresentations of safety. Plaintiffs and Class members reasonably relied on the misrepresentations made by Defendants.

153. Wherefore, as a direct and proximate result thereof, Plaintiffs and members of the Class are entitled to injunctive and equitable relief, and a full refund in the amount they spent on the BPO Products.

COUNT V

Unjust Enrichment
(On Behalf of all Plaintiffs against Defendants)

154. Plaintiffs incorporate by reference and re-allege each and every allegation contained above, as though fully set forth herein.

155. Plaintiffs bring this Count V on behalf of the Missouri and Florida Classes against Defendants.

156. Defendants profited exponentially from their marketing and sale of their benzene-contaminated BPO Products. Plaintiffs and Class members were deprived of the money paid for these defective and unsafe products.

157. Defendants were unjustly enriched by unlawfully receiving money from Plaintiffs for defective and unsafe products. It would be inequitable and unconscionable for Defendants to retain the compensation obtained based on its wrongful conduct.

158. Wherefore, as a direct and proximate result thereof, Plaintiffs and members of the Class are entitled to injunctive and equitable relief, and a full refund in the amount they spent on the BPO Products as well as an order from this Court requiring the disgorgement of all profits, benefits, and additional compensation obtained by Defendants by way of their wrongful conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and all others similarly situated, pray for judgment against the Defendants as to each and every count, including:

A. An order declaring this action to be a proper class action, appointing Plaintiffs and their counsel to represent the Class, and requiring Defendants to bear the costs of class notice;

B. An order requiring Defendants to pay restitution/damages to restore all funds acquired by means of any act or practice declared by this Court to be an unlawful, unfair, or fraudulent business act or practice, untrue or misleading advertising in violation of the above-cited authority, plus pre- and post-judgment interest thereon;

C. An order requiring Defendants to disgorge any ill-gotten benefits received from Plaintiffs and members of the Class as a result of any wrongful or unlawful act or practice;

D. An order requiring Defendants to pay all actual and statutory damages permitted under the counts alleged herein;

E. An order awarding attorneys' fees and costs to Plaintiffs and the Class; and

F. An order providing for all other such equitable relief as may be just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all issues so triable.

DATED: July 18, 2024

Respectfully,

/s/ Kiley L. Grombacher
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